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EXAMINER

SHEINBERG, MONIKA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/992,028

### Applicant(s)

FIRMAN, KEITH

### Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 16-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)  
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 sheets. 6) ☒ Other: detailed action.

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**DETAILED ACTION**

**Election/Restrictions**

Applicant's election of Group II (claims 2-15) in the response filed: 30 January 2003, is acknowledged. Unfortunately the entry had been delayed, therefore the Examiner would like to apologize for the delay in the response.

In regards to the election, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1 and 16-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse (as shown above) in the response filed: 30 January 2003.

Claims 2-15 are hereby examined.

**Sequence Non-Compliance**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because there are nucleic acid sequences within the specification that do not have a sequence identifiers: see pages 26, 29, 32, 34 and 36. A Sequence Listing and a computer readable format of it must be provided with a statement that the two are identical. The sequences presented in the specification must still be included in the Sequence Listing; and a sequence identifier (SEQ ID NO: X) must be used within the specification. Applicant is reminded that CD-ROM sequence listings are now accepted instead of a paper copy of the sequence listing for the specification. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. *A complete response to this office action includes compliance with this sequence rule compliance. Failure to comply may result in abandonment of this application.*

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claims 2-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-15 are vague and indefinite due to the lack of clarity of the term “capable of” line 3. It is unclear what are the metes and bounds of the parameters that define an enzyme’s capability. For example it is unclear if the enzyme is rendered capable if it provides enough force for translocation; is merely involved in, or associated with the mechanism/action of translocation; or is an actual translocating enzyme itself. As such claims 3-11 and 13-15 are also in definite due to dependency from claims 2 and 15.

Claims 2-15 are vague and indefinite due to the lack of clarity of the phrase “an enzyme capable of translocating the nucleic acid sequence without causing cleavage of the nucleic acid during the translocation” in lines 3-5 and 3-4, respectively. The lack of clarity lies in whether the cleavage is actually prohibited from occurring at all to meet the limitations of the claim, or the action of cleavage merely cannot occur *during* translocation. If the latter is intended then an enzyme which translocates an nucleic acid sequence and cleaves *afterwards* would fulfill the instant requirement of not cleaving during translocation. As such it is unclear what is intended to be encompassed by the claim. Claims 3-11 and 13-15 are also indefinite due to dependency from claims 2 and 15.

Regarding claim 10, the word “means” is preceded by the word(s) “the bound substance comprises [...]” in an attempt to use a “means” clause to recite a claim element as a means for performing a specified function, “means for binding”. Thus the body of the claim describes a method step for binding, while the composition being described, “the bound substance” is already bound. It is unclear as to what is intended by the applicant to be claimed, a method for binding the substance to the complex thus resulting in a “bound substance”; or another substance other than that already bound to the complex is to be added in addition to the already bound

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substance. The claim language is confusing, thus claim 10 is vague and indefinite due to lack of clarity.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- Claims 2-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Janscak *et al.* (*Nuc. Acids Res.*, 1-Oct-1998; *PTO-1449*).

Janscak *et al.* demonstrates restriction-modification systems (claim 2) of linear DNA-protein complexes (claim 3) that translocate bound plasmids into an unmodified host cell (abstract); wherein bound to the DNA is a Type IC HsdR subunit (claim 4 and 13) and a DNA methyltransferase (Mtase) subunit (claim 2), in a stoichiometry of HsdR<sub>1</sub>M<sub>2</sub>S<sub>1</sub> (claim 5 and 14) (abstract and p. 4442, Figure 3). The HsdR<sub>1</sub>M<sub>2</sub>S<sub>1</sub>-DNA complex is demonstrated to not cleave its bound DNA while still retaining ATPase activity (claims 2, 6 and 15) and translocation capability. The bound plasmid (nucleic acid sequence: claim 11) is a substance required to be translocated to an unmodified host cell, and is bound to the DNA-protein complex (claim 10). The Mtase is the second bound substance (claim 2, step 2) that can bind to a substance in solution (claim 7) for interaction with the environment of the system (ie. gel retardation assay, Figure 1, p. 4441) to produce a detectable and measurable effect (claim 11). The gel itself is a solid support (claims 8, 9 and 12).

- Claims 2, 3 and 7-12, are rejected under 35 U.S.C. 102(b) as being anticipated by Yin *et al.* (*Science*, 1995, *PTO-1449*).

Yin *et al.* demonstrates an RNA polymerase-DNA complex as a molecular motor translocating a nucleic acid that has a bead bound to the opposite end, while attached to a cover glass surface (claims 2 and 12) in solution (claim 7) (p. 1654, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph). (See

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also Figure 1, p. 1654). The RNA polymerase, a mecanoenzyme, is bound to one end of the linear DNA (claim 3) without cleaving it (claims 2 and 12, step 1); while a bead is attached at the opposite end (claim 2, step 2). The bead is "tethered to the surface by its connection through the DNA and the polymerase" (p. 1654, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph) thereby a "means for binding to the nucleic acid-enzyme complex" as required by claim 10. The glass cover slip is a solid support (claims 8 and 12) to which the DNA is attached opposite the bead (claim 9). The bead is a bound substance capable of movement and detected visually by the Brownian motion in light microscopy (claim 11).

- Claims 2-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Janscak *et al.* (*J. Mol. Biol.*, 1996; *PTO-1449*).

Janscak *et al.* teaches a DNA-protein complex comprising a type IC restriction-modification enzyme and exhibits the stoichiometric form HsdR<sub>1</sub>M<sub>2</sub>S<sub>1</sub> when bound to the second substance, methyltransferase (M<sub>2</sub>S<sub>1</sub>) (bridging paragraph of pp. 979-980). As per the MPEP 2112, Janscak *et al.* anticipates the molecular motor system of the instant claims being that the composition of the molecular motor system is identical to the instant composition of the claims thus inherently has identical properties.

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01.  
[2112.01]

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.).

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- Claims 2-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mernagh *et al.* (*Biol. Chem.*, April-1998; *PTO-1449*).

Mernagh *et al.* teaches a DNA-protein complex comprising a type IC restriction-modification enzyme and exhibits the stoichiometric form HsdR<sub>1</sub>M<sub>2</sub>S<sub>1</sub> when bound to the second substance, methyltransferase (M<sub>2</sub>S<sub>1</sub>) (p. 502, 2<sup>nd</sup> column, 3<sup>rd</sup> paragraph). As per the MPEP 2112.01 (see above), Mernagh *et al.* anticipates the molecular motor system of the instant claims being that the composition of the molecular motor system is identical to the instant composition of the claims thus inherently has identical properties.

### **Specification Objection**

The disclosure is objected to because of the following informalities: content of the specification does not follow the appropriate MPEP requirements. (See insert below). Appropriate correction is required.

#### **Content of Specification**

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.  
  
Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.
- (e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
  - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
  - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

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- (f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet (37 CFR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (k) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

### Conclusion

- Sequence Non-Compliance.
- Claims 2-15 are rejected under 35 U.S.C. 112, second paragraph.
- Claims 2-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Janscak *et al.* (1998).
- Claims 2, 3 and 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Yin *et al.*

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- Claims 2-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Janscak *et al.* (1996).
- Claims 2-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mernagh *et al.*
- Objection to the Specification.

No claim is allowed.

### *Inquiries*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Souaya, can be reached at 703-308-6565. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

August 25, 2003  
Monika B. Sheinberg  
Art Unit 1634

*MS*

JEHANNE SOUAYA  
PATENT EXAMINER

*Jehanne Souaya*  
*August 25, 2003*